REMARKS

Claims 50-100 are currently pending in the present application.

Applicants have amended claims 73, 75 and 77 to provide antecedent basis for the plastic strips. Claim 93 has been amended for clarity to recite a removable medical device. No new matter has been added.

Applicants respectfully remind the Examiner of the injector device assembly demonstrated in the interview conducted November 27, 2007. During that interview, Applicants' representatives demonstrated the device and emphasized three features present in the device:

1. Preloading of a removable insertion set within the device housing to be provided to the patient in a ready-to-insert configuration, thus avoiding manipulation of the insertion set onto the inserter by the patient;
2. Containment in a secured and stable fashion of the insertion set within the device housing and the cover for delivery to the patient; and
3. Maintenance of sterility for delivery of the ready-to-insert insertion set to the patient.

Independent claims 50, 72, and 90 herein have already been amended to recite a cover connectable to the housing as was suggested by the Examiner during the interview. As previously presented, claims 50, 72, 90, 97 and 100 further recite an insertion set removably mounted in the device housing. Claim 93 requires a removable medical device. Claims 50, 72, 90, 97 and 100 also require a sterile insertion set where the cover assures sterility of the insertion set prior to removal of the cover. The Examiner has shown no art that discloses these features.

In the present Office Action, the Examiner's rejections continue the pattern of rejecting Applicants' claims over art that relates to devices that are completely different from claimed invention. As discussed in further detail below, Miskinyar is another example of an innoculator where nothing is configured to be removably mounted in the device housing and then placed on the skin of the patient. Safabash (a CIP of the Funderburk reference previously cited) is another example of an inserter that does not even contemplate a cover connectable to the device housing and configured to assure sterility of the insertion set prior to the removal of the cover.

Applicants respectfully request reconsideration.

I. Interview Summary

Applicants thank the Examiner for sending the interview summary to indicate that the Supplemental Amendment filed on December 7, 2007 had been considered by the Examiner in the Office Action mailed January 17, 2008. On page 2 of the Office Action, the Examiner indicated that the Office Action was responsive to the communication filed on October 30, 2007 and that claims 50-100 were pending. Applicants thank the Examiner for making the clarification that the Supplemental Amendment filed on December 7, 2007 including new claims 97-100 had been considered.

II. Claim Rejections Under 35 U.S.C. § 112

Claims 73-77 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Applicants have amended claims 73, 75 and 77 to provide antecedent basis for the term "strips." Applicants respectfully request that the rejection of claims 73-77 under 35 U.S.C. § 112, second paragraph, be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 102

A. Claims 72, 78, 80-88 and 90-100

Claims 72, 78, 80-88 and 90-100 have been rejected under 35 U.S.C. 102(b) as being anticipated by Miskinyar (U.S. 5,527,287).

Applicants respectfully traverse the rejection of claims 72, 78, 80-88 and 90-100 as being anticipated by Miskinyar. Applicants' claim 72 requires a sterile insertion set with a housing and a hollow cannula where the insertion set is positioned within the device housing for delivery of the sterile insertion set to the patient. The insertion set is separable from the plunger after placement of the cannula. Claim 90 requires placing an insertion set with the injector device housing. Claim 93 requires a removable medical device. Claim 97 requires an insertion set positioned removably from and within the device housing. Claim 100 recites placing the insertion set with the injector device housing so that the piercing member extends at least partially through the cannula of the insertion set. A removable

insertion set is clearly not taught or suggested by Miskinyar. Miskinyar further clearly fails to teach or suggest a sterile insertion set contained within a device housing and a cover.

According to the Examiner, Miskinyar teaches a sterile insertion set with housing 74. This is incorrect. As described in the specification, the element 74 is an ampoule 74 that is contained within the ampoule chamber 24. In fact, the ampoule 74 is formed by an elastic balloon which is received within and **sealed** to the inner walls of the ampoule chamber. (Col. 3, lines 60-64.) Miskinyar does not teach or suggest any removable insertion device for placement by an injector. Miskinyar is directed a preloaded automatic disposable syringe. The syringe of Miskinyar includes an ampoule connected to a hypodermic needle that is slidably received in the housing. The needle projects from the housing and medication is discharged into the patient from the ampoule through the needle by an actuator spring. (Abstract.) Clearly, Miskinyar fails to teach or suggest a device that is removably enclosed by the housing, placeable on the skin of a patient and at least a portion of which is separable from the inserter.

Therefore, Applicants respectfully request that the rejection of claims 72, 78, 80-88 and 90-100 under 35 U.S.C. 102(b) be withdrawn.

B. Claims 50-57, 59, 65-68, 72, 78-85, 89, 93-99

Claims 50-57, 59, 65-68, 72, 78-85, 89 and 93-99 have been rejected under 35 U.S.C. 102(e) as being anticipated by Safabash et al. (U.S. 6,293,925).

Applicants respectfully traverse the rejection of claims 50-57, 59, 65-68, 72, 78-85, 89 and 93-99 as being anticipated by Safabash. Independent claims 60, 72, 90, 93 and 97 each require a cover connected to a portion of a device **housing.** Claims 50, 72, 90 and 97 also require a sterile insertion set where the cover assures sterility of the insertion set prior to removal of the cover. Safabash clearly fails to teach or suggest a cover connected to a portion of the device housing and further fails to teach or suggest that the cover assures sterility of the insertion set prior to removal of the cover.

According to the Examiner, Safabash teaches a cover 414. According to the specification, the element 414 is a piercing member guard (or needle guard) that the user presses against to seat the piercing member hub 408 (or needle hub) and the insertion set 400 in the cavity 514 of the carrier body 504. (Col. 19, lines 27-30.) As shown in FIG.

40d, the user removes the piercing member guard 414 (normally by twisting) to expose the piercing member 402 while maintaining the insertion set 400 within the carrier body 504. (Col. 19, lines 42-45.) Clearly, the guard 414 of Safabash is only a needle cover that is secured over the needle of the separable insertion set 400 only and is not connected to the device housing. Further, the needle cover 414 cannot assure sterility of the insertion set prior to the removal of the cover connected to the housing since the insertion set of Safabash is exposed and placed in the housing by the user as shown in FIGS. 40a-d. The device shown in Safabash is not configured for sterilization, and further does not provide secure containment for the insertion set. The purpose of the Safabash cover is completely different and serves only to cover the needle. Safabash clearly fails to teach or suggest a cover where the cover is connected to the device housing and further that the cover assures sterility of the insertion set prior to removal of the cover from the housing.

Therefore, Applicants respectfully request that the rejection of claims 50-57, 59, 65-68, 72, 78-85, 89 and 93-99 under 35 U.S.C. 102(e) be withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 103

A. Claim 58

Claim 58 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash and further in view of Teeple, Jr. (U.S. 5,807,316). Teeple has been cited for encoding the shelf life on a device.

Applicants respectfully traverse the rejection of claim 58. Safabash has been discussed above and fails to teach the claimed invention in claim 50. Teeple is directed to a method and an apparatus for preparing and administering intravenous anesthesia infusions. (Abstract) Teeple fails to make up the deficiencies of Safabash.

Therefore, Applicants respectfully request that the rejection of claim 58 under 35 U.S.C. 103(a) be withdrawn.

B. Claims 69-71, 86-88, 90-92 and 100

Claims 69-71, 86-88, 90-92 and 100 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash and further in view of Miskinyar.

Applicants respectfully traverse the rejection of claims 69-71, 86-88, 90-92 and 100. Applicants respectfully assert that the teachings of Safabash and Miskinyar are not sufficient to render the claims *prima facie* obvious as required by § 103(a).

Miskinyar has been discussed above and is directed to an injector having an ampoule connected to a needle to deliver a fluid to a patient. Miskinyar fails to teach or suggest an insertion set removably enclosed by the housing and placeable on the skin of a patient. The syringe of Miskinyar is preloaded with a precisely measured dosage of medication and has the proper selection of needle size for the patient. (Col. 4, lines 9-11.) In other words, the device of Miskinyar only delivers a fluid to the patient.

Safabash has also been discussed above and fails to teach or suggest an injection device having a cover connected to the housing. Safabash further fails to teach or suggest that the cover assures sterility of the insertion set prior to the removal of the cover. Safabash teaches an open-ended injector where the user must manually attach the insertion set to the injector. The injector of Safabash is particularly designed to safeguard against undesired projection of the medical needle through free space. (Col. 2, lines 14-17.) Safabash already includes several different features for preventing accidental firing of the device and thus, one skilled in the art would not be motivated to look to Miskinyar for a feature to prevent accidental firing as suggested by the Examiner on page 4 of the Office Action. In addition, the injectors disclosed by Safabash include multiple parts that are pieced together as well as slots and cut outs along the side of the barrel to accommodate infusion tubing and wings on the insertion set. One could not simply add covers to each end of Safabash and assure sterile conditions of the insertion set within the housing. One skilled in the art would not be motivated to combine Safabash and Miskinyar. It is therefore suggested that the Examiner's rejection is improperly looking to the disclosure of Applicants' specification to combine Safabash and Miskinyar. Such analysis is based on impermissible hindsight.

Therefore, Applicants respectfully request that the rejection of claims 69-71, 86-88, 90-92 and 100 under 35 U.S.C. § 103(a) be withdrawn.

V. Allowable Subject Matter

Applicants kindly thank the Examiner for indicating that claims 60-64 are allowed.

VI. SUMMARY

It is respectfully asserted that the claims properly define the invention and that the invention is both novel and non-obvious. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,

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Date

Heidi A. Dare (Reg. No. 50,775)

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4809